Society for the Advancement of
WOMEN'S HEALTH RESEARCH

Food and Drug Administration
Dockets Management Branch
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

September 11, 1998

Re: Docket Number 98N-0339

The Society for the Advancement of Women's Health Research is pleased to submit comments on how the Food and Drug Administration may best meet its statutory obligations under the Federal Food, Drug, and Cosmetic Act.

We believe the FDA must:

- Have statistically significant numbers of women included in pharmaceutical testing to identify gender-related differences in drug responses and that noted differences be analyzed;
- Have access to the latest scientific and technical expertise in gender-based science;
- Strengthen its post-marketing surveillance system, in general, so that problems are identified early; and collate data with attention to gender, age, and ethnicity;
- Have labeling contain specific reference to gender, age, and ethnicity if differences are known;
- Draft and codify proactive regulatory guidelines for the evaluation, approval and marketing of vaginal microbicides/contraceptives; and
- Make it clear to Congress and the Administration the resources it needs to assure the safety and efficacy of drugs in this time of accelerated new therapies and technologies.

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Gender-based Research

The Society is concerned that the Agency has the ability to independently ascertain and analyze gender differences in drug responses. Although a body of data is emerging, there is much that is still unknown about the role of gender in drug effects in women. Only with a strong scientific and research infrastructure will the FDA improve its ability to expedite new technologies for women and prevent potential adverse reactions in women from new products.

Previous restrictions on the participation of women in early phases of clinical trials limited knowledge about drug responses in women, about the relationships between dose and efficacy and the variability of response in different patient populations. Most drugs marketed today were approved without the benefit of testing in women. Studies have demonstrated gender differences in several mechanisms of drug absorption, bioavailibility, distribution, metabolism and elimination. For example, most psychotropic drugs, which are absorbed by the liver, are affected by gender, phase of a woman's menstrual cycle and exogenous hormones, like birth control pills. Studying currently available gender-based data with reference to a baseline could yield significant findings.

The Society is most interested in the FDA recognizing the need to continually employ scientists knowledgeable and in the forefront of gender-based pharmacological research. It urges support for grants in training for clinical pharmacologists interested in gender-based research. Through recruitment, retention and education of professional staff, the FDA will attract and retain scientists at the cutting edge of science. The Society believes that this would demonstrate the FDA's recognition of the most up-to-date science-based decision-making.

Gender Analysis In Post-market Surveillance

As drugs are moved more rapidly through the approval pipeline, the need for strengthening the FDA post-market surveillance program becomes more urgent. Increasing numbers of adverse event reports demand more professionals to analyze the data.

Likewise, a post-market surveillance system should include analysis of data by gender. In a recent study appearing in the *Journal of the American Medical Association*, serious adverse drug reactions in US hospitals were found to be very high, even when drugs were prescribed and administered properly. According to the Centers for Disease Prevention and Control, women from 15-64 visit hospital emergency rooms and outpatient clinics 66 percent more than men and the average length of hospital stay for women over 65 years is slightly longer than for men. Women make the majority of physician visits and are responsible for the

majority of prescription drug purchases. Some research studies have concluded that women experience more adverse drug reactions than men, a likely consequence of the previously cited data as well as other potential factors.

Utilizing computer-based information technology to record and explore gender differences has the potential for preventing serious medication hazards. Gender-based analysis of adverse drug reactions also could provide this information more rapidly, particularly when women are taking more medication and their incidence of adverse reactions may be greater. Analysis of data with attention to age and ethnicity also could yield significant results.

Gender-based Information

As gender-based pharmaceutical research yields new information for men and women, health care providers and consumers should be informed. They need to be made aware of varying dosage and possible reactions. Labeling information should include appropriate gender, age and ethnic information, when available.

Guidelines for Microbicides/contraceptives

These products are used by healthy women over a long period of time. Microbicides, in particular, are not viewed as financially rewarding by manufacturers. However, there is a great and growing need to halt the spread of sexually transmitted diseases. At the same time, several FDA centers, offices and divisions can be required to review these products.

As a member of the Alliance for Microbicide Development, we support their recommendation to review the current guidelines for consistency; systematically examine them in light of the latest evolving knowledge; and incorporate new information. We also support the need for clear, consistent and efficient processes for review and approval of microbicides/contraceptives.

Adequate Resources

The fact that the FDA is faced with severe concerns about meeting its statutory obligations denotes the financial constraints under which it is operating. In addition to informing stakeholders about the realities of the shortfall, the FDA should let Congress and the Administration know about the costs of maintaining adequate resources and programs through its planning process and budget proposals. The FDA should develop estimates reflecting the professional judgement of its leadership. Stakeholders will support the Agency to secure adequate funding to meet FDA's obligations.

In conclusion, thank you for the opportunity to provide comments as the FDA works toward meeting the statutory obligations of FDAMA. The Society will be glad to work with the Agency to assist it in meeting its goals.

Sincerely,

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Executive Director

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